



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

March 23, 2020

Re: Animal Welfare Assurance  
A3472-01 [OLAW Case 5L]

Dr. David Russell  
Vice President and Dean of Basic Research  
University of Texas Southwestern Medical Center  
5323 Harry Hines Boulevard  
Dallas, TX 75390-9002

Dear Dr. Russell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 13, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Southwestern Medical Center. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the UT Southwestern Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without appropriate IACUC review and approval and failure to adhere to IACUC-approved protocols. The final report states on September 26, 2019 animal facility staff found a mouse unattended in the vivarium that appeared anesthetized but was found to be deceased on closer exam. The research staff member was immediately counselled by the Clinical Veterinarian and counselled by Sr. IACUC Liaison on October 4, 2019. A post-approval monitoring visit was conducted on October 16, 2019 to observe PI's post-surgical animals and no concerns were observed. A PAM visit November 4, 2019 revealed issues with the staff member's aseptic technique and the person was counseled by Sr. IACUC Liaison and Clinical Veterinarian. The following day a PAM visit revealed noncompliance with the approved protocol, the following findings were reported:

- Drilling two burr holes for intracranial injection instead of one hole as approved per protocol.
- Failure to apply bone wax as per protocol.
- Unapproved application of 30% hydrogen peroxide to the skull.
- The performance of unapproved ear notching for animal identification.
- Administration of an unapproved doxycycline diet.

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The Assistant Vice President for COI & IACUC and the IACUC Chair counseled the PI on November 21, 2019 and the research staff member voluntarily ceased performance of the surgical procedure until hands-on surgical retraining and a subsequent successful PAM visit could occur. An amendment was submitted to add the unapproved work to the protocol, and it was approved on December 6, 2019. The staff member completed retraining on December 19, 2019. The lab confirmed to the IACUC on February 19, 2020 that they did not plan to perform surgery again in the near future. A note was placed in the protocol indicating that this staff member is not approved to perform surgery.

It is noted that this research was supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Texas Southwestern Medical Center has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3472-5L

**UT Southwestern**  
Medical Center

**David W. Russell, Ph.D.**  
Vice Provost and Dean of Research  
UT Southwestern Medical School  
Department of Molecular Genetics  
Eugene McDermott Distinguished Chair

March 13, 2020

Brent Morse, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

RE: UT Southwestern Medical Center Animal Welfare Assurance Statement # D16-00296  
Grant: R01NS056224

Dear Dr. Morse,

I write to provide a final report of non-compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals* regarding an incident on September 26, 2019 in which animal facility staff found a mouse unattended in the vivarium that appeared to be anesthetized but upon a closer look was deceased. The research staff member was immediately counseled by the Clinical Veterinarian.

The Sr. IACUC Liaison counseled the research staff member on October 4, 2019. A post-approval monitoring visit was conducted on October 16, 2019 to observe the PI's post-surgical animals and there were no concerns. During a post-approval monitoring visit on November 4, 2019, issues were noted with the staff member's aseptic technique and the staff member was counseled by the Sr. IACUC Liaison and Clinical Veterinarian. During a subsequent post-approval monitoring visit on November 5, 2019, noncompliance with the approved protocol was observed including the drilling of two burr holes for intracranial injection instead of one hole as per protocol, failure to apply bone wax as per protocol, the unapproved application of 30% hydrogen peroxide to the skull, the performance of unapproved ear notching for animal identification, and the administration of an unapproved doxycycline diet. The Sr. IACUC Liaison and Clinical Veterinarian counseled the research staff member during this visit.

The Assistant Vice President for COI & IACUC and the IACUC Chair counseled the PI on November 21, 2019 and the research staff member voluntarily ceased performance of the surgical procedure until hands-on surgical retraining and a subsequent successful post-approval monitoring visit could occur. An amendment to add the unapproved work to the protocol was approved on December 6, 2019.

The staff member completed retraining on December 19, 2019; however, the laboratory confirmed to the IACUC on February 19, 2020 that they did not have plans to perform surgery again in the near future. Therefore, the required post-approval monitoring visit to assess the staff member's competency following retraining could not occur. A note was placed in the protocol indicating that this staff member is not approved to perform surgery.

We believe the actions taken by the IACUC are appropriate for this situation.

Yours sincerely,

(b) (6)

David W. Russell, Ph.D.  
Vice Provost, Dean of Research, and Institutional Official

5323 Harry Hines Blvd., Dallas, Texas 75390-9046 Phone: 214-648-2007 Fax: 214-648-8955 david.russell@utsouthwestern.edu  
utsouthwestern.edu

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, March 19, 2020 6:33 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report to OLAW

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Wednesday, March 18, 2020 7:31 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) David Russell <David.Russell@UTSouthwestern.edu>  
**Subject:** Report to OLAW

To the Division of Compliance Oversight,

Attached is a final report of non-compliance. Please let me know if you have any questions regarding this report.

(b) (6)

(b) (6)

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## UT Southwestern

Medical Center

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